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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,604	09/29/2005	Robert William Lachlan Holmes	4516-1004	4121

466 7590 09/11/2008

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EXAMINER	
KASSA, TIGABU	
ART UNIT	PAPER NUMBER
4161	

MAIL DATE	DELIVERY MODE
09/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,604	HOLMES ET AL.	
	Examiner	Art Unit	
	TIGABU KASSA	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08). Paper No(s)/Mail Date *04/18/2005 and 01/18/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-11 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 04/18/2005 and 01/18/2005 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 recites the limitation "the glycol ethers" in claim 1. There is insufficient antecedent basis for this limitation in the claim. It will be remedial to amend the claims to indicate the dependency. Examiner also requests that proper Markush group language should be used (i.e. "a solvent selected from the group consisting of glycol ethers").

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-11 are vague and indefinite because of the use of the term "comprising" in Markush language set up. According to MPEP 2173.05(h) it is improper to use the term "comprising" instead of "consisting of" in Markush claims (see Ex parte Dotter, 12 USPQ 382 (Bd. App. 1931)). The use of Markush claims of diminishing scope should not, in itself, be considered a sufficient basis for objection to or rejection of claims. However, if such a practice renders the claims indefinite or if it results in undue multiplicity, an appropriate rejection should be made. The Markush is indefinite, because it is unclear what species make up the group being recited.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention .

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating infection of cattle with Cooperia or Ostertagia through the administration of the formulation, does not reasonably provide enablement for the prevention of infection of cattle with Cooperia or Ostertagia. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope of breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1. *The breadth of the claim*: Claim 11 is drawn to a method of treating or preventing infection of cattle with Cooperia or Ostertagia using the anti-parasitic formulation. The scope of the claim is broad.
2. *Nature of the invention*: "Prevention" is interpreted in the absolute sense to mean no occurrence of parasitic infection. Claim 11 is drawn to a method of treating or preventing parasitic infection in animals by administering applicant's claimed formulation.
3. *The state of the prior art*: Method of treating parasitic infection in animals is well-known in the art using various formulations for example see Harvey (US Patent No. 6,165,987). However, the prior art is unequivocal with regards to prevention:

"Despite substantial investment and research, the prevention of parasitic infections for example in humans is dependant of avoidance strategies since no vaccines are available" (www.merck.com/mmpe/print/sec14/ch181/ch181a.html). Additionally, the prior art teaches that compositions comprising anthelmintic agents can be used for treating parasitic infections in animals (for example see Harvey US Patent No. 6,165,987). Harvey is silent on prevention, which is interpreted as implying prevention is not in the purview of the prior art.

4. *Level of one of ordinary skill in the art*: One of ordinary skill in the art would include clinicians and scientists researching veterinary medicine (DVM).
5. *Level of predictability in the art*: There is relatively little unpredictability in the art with regards to treating versus preventing parasitic infection. Preventing parasitic infection using formulations is not currently possible.
6. *Amount of direction provided by the inventor*: Although, the instant specification discloses a method of treating parasitic infections in animals, applicants offer no guidance as to how to prevent parasitic infections using the claimed method.
7. *Existence of working examples*: The specification fails to provide scientific data and working embodiments with respect to prevention of parasitic infection.

Quantity or experimentation needed to make or use the invention based on the content of the disclosure: To use the invention as claimed, one of ordinary skill in the art would be required to conduct an undue amount of experimentation, to reasonably and accurately determine whether the composition and the corresponding method of the instant application does in fact prevent parasitic infection.

In conclusion, it is readily apparent from the aforementioned discussion, in conjunction with the lack of scientific data and working embodiments regarding the prevention of parasitic infection, that one of ordinary skill in the art would be required to conduct an undue amount of experimentation to determine how to prevent parasitic infection in cattle by administrating applicant's formulation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, and 7-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Komer (US Patent No 5,773,422). Instant claim 1 recites a stable formulation for administration to animals including at least one anti-parasitic agent dissolved in a pyrrolidone solvent. In other embodiments, such as instant claim 3, the pyrrolidone solvent is 2-pyrrolidone or N-methyl pyrrolidone. Instant claim 4 recites that the avermectin or milbemycin is present in the range of between 0.01-5% w/v. In further limitations instant claim 5 recites in the formulation is selected from the list of abamectin, doramectin, eprinomectin, ivermectin, and moxidectin. Instant claim 7 recites the formulation additionally includes at least one medicament selected from the list recited in the instant claim. Komer discloses novel formulations for the administration of an avermectin dissolved in N-methylpyrrolidone or 2-pyrrolidone or mixtures thereof (see Abstract and claim 1). This addresses the limitations recited in instant claims 1 and 3.

Komer discloses that the avermectin in the invented formulation is ivermectin, which is found in concentration of 1% (w/v) (column 3, lines 24-25 and claim 2). This addresses the limitations recited in instant claims 4 and 5.

Komer discloses the incorporation of other medicaments such as clorsulon, which is an additional active agent in the formulation in addition to ivermectin (column 4, lines 58-60). Furthermore, Komer also discloses the incorporation of methylparaben and propylparaben (column 5, example 11), which are known preservatives that can be considered as other beneficial agents. This addresses the limitations recited in instant claim 7

Instant claims 8-10 claim a formulation for administration to animals in a form for topical, parenteral, or oral administration.

Komer discloses that the novel formulations are suitable for administration by intramuscular or subcutaneous injection, by topical application, stomach intubation, oral and drench administration (see Abstract). Furthermore, Komer discloses illustrative working examples for the different routes of administration, such as injectable, pour-on (topical) formulation, and oral formulations (see column 4, lines 30-67 and all column 5 and column 6, lines 1-31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komer (US Patent No 5,773,422) in view of Huet et al. (US Patent No 6,426,333) and Harvey (US Patent No 6,165,987).

Applicant Claims

Applicant claims a stable formulation as described above in the instant office action, wherein in some embodiments, such as in instant claim 2, the formulation further comprises an additional solvent selected from the glycol ethers.***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

As discussed above the required limitations of instant claim 1 are addressed by the teachings of Komer. Additionally, Komer teaches the formulation further comprises other cosolvents such as propylene glycol (column 3, lines 10-11)

Huet et al. disclose spot-on formulation for combating parasites comprising an effective amount of a 1-phenylpyrazole derivative; and/or, an effective amount of a macrocyclic lactone or antiparasitic agent; an acceptable liquid carrier vehicle; and optionally, a crystallization inhibitor (column 4, lines 39-67 and column 6, lines 1-30). Huet et al. disclose that "the liquid carrier vehicle comprises a solvent wherein the solvent is selected from the group consisting of, dipropylene glycol n-butyl ether, ethylene glycol monoethyl ether, ethylene glycol monomethyl ether, dipropylene glycol monomethyl ether, diethylene glycol monoethyl ether, which are glycol ethers (column 6, lines 5-20).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Komer lacks the teaching of formulations comprising glycol ethers as an additional solvent. This deficiency is cured by the teachings of Huet et al.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to an ordinary skilled artisan at the time the instant invention was made to modify the formulation of Komer by incorporating additional solvents like glycol ethers as taught by Huet et al., because Harvey discloses that the anthelmintic agents need to be administered as solutions by dissolving them in solvents such as glycol ethers to be bio-available; because the solid dosage forms are poorly absorbed by the

animal (column 1, lines 22-25). The Harvey reference is used to demonstrate the general state of the art with regard to the use of solvents such as glycol ethers in anthelmintic formulations. Furthermore, the glycol ethers are commonly known solvents in the art for providing advantages of improved stability and extended shelf life to the formulations, when compared to solid dosage forms of said anthelmintics administered to animals. A skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings because Komer, Huet et al., and Harvey teach within the same field of endeavor and address the same problem, namely the treatment of parasitic infections.

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komer (US Patent No 5,773,422) in view of Harvey (GB Patent Application No 2252730).

Applicant Claims

Applicant claims a stable formulation as described above wherein the composition comprises a levamisole that is present in the range of between 1-30% w/v.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

As discussed above the required limitations of instant claim 1 are addressed by the teachings of Komer. Additionally, Komer teaches the incorporation of other medicaments, such as clorsulon, in the formulation in addition to ivermectin (column 4, lines 58-60).

Harvey (GB Patent Application No 2252730) teaches anthelmintic compositions containing praziquantel together with at least one other anthelmintic compound, for example

levamisole (see abstract). Harvey (GB Patent Application No 2252730) also teaches a typical formulation praziquantel from 0.5-15% w/v and levamisole 1-10% w/v (see page 3, general formulation) and gives an illustrative example (see page 4, example 1).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Komer lacks the teaching of formulations comprising levamisole in an amount of 1-30% w/v. This deficiency is cured by the teachings of Harvey (GB Patent Application No 2252730).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to ordinary skill in the art at the time of the instant invention to combine the teachings of Komer and Harvey, because Harvey discloses that formulations containing combinations of anthelmintic agents can be used to overcome drench resistance, which is caused by resistance to the effects of particular compounds (page 1, see background). For instance, Harvey discloses that ivermectin is active against parasitic roundworms but inactive against tapeworms (page 1, see background). A skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings because both Komer and Harvey teach within the same field of endeavor and address the same problem, namely the treatment of parasitic infections.

Claims 1 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komer (US Patent No 5,773,422, Issued on June 30, 1998) in view of Harvey (US Patent No 6,165,987, IDS reference).

Applicant Claims

Applicant claims a method of treating or preventing infection of cattle with Cooperia or Ostertagia by administering a formulation recited in claim 1, as described above in the instant office action.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

As discussed above the required limitations of instant claim 1 are addressed by the teachings of Komer.

Harvey (US Patent No 6,165,987) teaches "a veterinary composition containing an effective amount of praziquantel, an effective amount of at least one macrolide anthelmintic selected from the group comprising the avermectins and the milbemycins, and a suitable organic solvent selected from the group consisting of glycerol formal, ethyl lactate, benzyl alcohol and N-methyl-2-pyrrolidone and the like, wherein the composition is suitable for administration to warm-blooded non-human animals. The composition may be a solution or a paste and may be administered to the recipient animal by injection, drench or as an oral paste. A method of treating endo- and ectoparasites in non-human animals is also claimed" (see abstract and claim 13). Harvey (US Patent No 6,165,987) also discloses that "target parasite species were Haemonchus, Ostertagia, Trichostrongulus, Cooperia, Nematodirus, Oesophagostomum, Chabertis and Monezia expansa" for treatment (column 10, lines 27-30). Ostertagia and Cooperia refer to two parasitic genera and that Harvey's method is suitable in the treatment of species of each genera. A species necessarily anticipates and obviates it corresponding genus.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Komer lacks the teaching of a method of treating or preventing infection of cattle with *Cooperia* or *Ostertagia* by administering a formulation recited in claim 1. This deficiency is cured by the teachings of Harvey.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to a person of ordinary skill in the art at the time the instant invention was made to modify the method of Komer via treating parasitic infections caused by the species *Cooperia* or *Ostertagia* as taught by Harvey, because both *Cooperia* or *Ostertagia* are commonly known parasitic species that infect animals that are targeted for treatment by antiparasitic formulations as also demonstrated by Harvey. A skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings because both Komer and Harvey teach within the same field of endeavor and address the same problem, namely the treatment of parasitic infections, which are caused by the parasitic species like *Cooperia* or *Ostertagia*..

Conclusion

Claims 1-11 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 9/7/08

/John Pak/
Primary Examiner, Art Unit 1616